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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,834	08/08/2006	Yasuhiro Isogai	023312-0117	6295
22428 7590 05/21/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER MCDOWELL, BRIANE	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 05/21/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,834

**Applicant(s)**

ISOGAI ET AL.

**Examiner**

BRIAN MCDOWELL

**Art Unit**

1624

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11,13,14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 10/20/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

/BEM/

**DETAILED ACTION**

***Status of Claims***

Claims 1, 3-8, 11, and 13-14 are pending in the instant application.

***Status of Priority***

Applicant's arguments, see Remarks, filed 4/10/2009, with respect to the denial of foreign priority set forth in the Non-Final Office Action mailed 12/30/2008, have been fully considered and the instant application receives the priority date of 4/21/2003.

***Information Disclosure Statement***

Applicant's arguments, see Remarks, filed 4/10/2009, with respect to the non-compliant IDS set forth in the Non-Final Office Action mailed 12/30/2008, have been fully considered and the IDS has now been considered by the examiner.

***Status of Claim Objections***

Applicant's amendment of claims 13 and 14, see Remarks, filed 4/10/2009, with respect to the objection set forth in the Non-Final Office Action mailed 12/30/2008, has been fully considered but are not found persuasive. The claims still embrace non-patentable for use limitations. For example, the preamble of claim 13 should more appropriately be written as "A diagnostic agent comprising.....". Appropriate correction is required.

***Status of Rejections***

***35 USC § 112 (2<sup>nd</sup> Paragraph)***

Applicant's amendment of claim 1, see Remarks, filed 4/10/2009, with respect to the rejection of claims 1-4, 6-8, 11, 13, and 14 set forth in the Non-Final Office Action mailed 12/30/2008, has been fully considered and the rejection has been overcome.

***35 USC § 102***

Applicant's amendment of claim 1, see Remarks, filed 4/10/2009, with respect to the rejection of claims 1,11, and 13 set forth in the Non-Final Office Action mailed 12/30/2008, has been fully considered and the rejection has been overcome.

Applicant's arguments, see Remarks, filed 4/10/2009, with respect to the rejection of claims 1-8, 11, 13, and 14 set forth in the Non-Final Office Action mailed 12/30/2008, have been fully considered and the rejection has been overcome.

**35 USC § 103**

Applicant's arguments, see Remarks, filed 4/10/2009, with respect to the rejection of claims 1-8,11,13, and 14 set forth in the Non-Final Office Action mailed 12/30/2008, have been fully considered and the rejection has been overcome.

***New Objections and Rejections***

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "wherein the Por is a porphyrin residue selected from a group consisting of uroporphyrin-I, uroporphyrin-II, coproporphyrin-III,

protoporphyrin-IX, and hematoporphyrin-IX". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botti *et al.* (WO 03/016330-newly cited, mentioned in IDS) in view of Roelant *et al.* (US Patent 5,998,128).

Instant claims 1, 3-7, 11, 13, and 14 are drawn to porphyrin compounds linked to biotin groups via hydrocarbyl or heterohydrocarbyl linkers.

Botti *et al.* teach porphyrins that are linked to biotin through heterohydrocarbyl linkers that are applicable in purifying G protein-coupled receptors (see end of document, drawings section, page 4/9, Fig. 6a). However, this document does not teach biotin-linked porphyrins where the porphyrins are hemes or derivatives thereof (e.g., heme a, heme c, etc.).

Roelant *et al.* disclose several heme-like porphyrins (including the instantly claimed heme-b). Furthermore, this document discloses that the aforementioned porphyrins serve as excellent binding substrates and may consequently be used in

processes for labeling, detecting, and quantifying chemical/biological entities (e.g., proteins, see abstract and col.2, lines 12-14).

Based on the teachings above it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to substitute a porphyrin such as heme b or a similar derivative thereof (e.g., heme a, heme c, etc.) into the biotin-linked compound described by Roelant and consequently use this compound in one of the processes described above (e.g., purifying or quantifying proteins, in particular hemoproteins since one of ordinary skill is aware that heme readily binds to said proteins). Therefore, the claims are obvious.

Claim 8 is drawn to a method of preparing a biotinyl linked porphyrin by coupling said porphyrin with a terminally aminated biotinyl group in the presence of a coupling agent. This method is described in the Roelant document, where DCC and hydroxybenzotriazole (see page 51, lines 20-30) are used as the coupling agents. Thus, this method of preparation would be considered obvious.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. M./  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner , Art Unit 1624